

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Takuya Tamatani et al.	Art Unit :	1644
Serial No. :	10/721,404	Examiner :	Ilia I. Ouspenski
Filed :	November 25, 2003	Conf. No. :	1646
Title :	METHODS OF IDENTIFYING SUBSTANCES THAT INTERACT WITH JTT-1 PROTEIN		

**Mail Stop AF**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicants submit this request under the Pre-Appeal Conference Pilot Program described in the U.S. Patent and Trademark Official Gazette Notice, "New Pre-Appeal Brief Conference Pilot Program," dated July 12, 2005 and extended until further notice as of January 10, 2006. This request is being filed with a Notice of Appeal.

**Status of Claims and Summary of Rejections**

Claims 53-59, 64-66, 68, and 69 are pending in the application. In the final Office Action dated January 8, 2007, claims 53-59, 64-66, 68, and 69 were (i) asserted to lack adequate support in priority application USSN 09/383,551, (ii) rejected as obvious, and (iii) provisionally rejected on the basis of obviousness-type double patenting. Applicants filed a response to the final Office Action on March 26, 2007 and the rejections were maintained in an Advisory Action dated April 17, 2007.

Each of the three rejections identified above is addressed in the following sections. However, it is applicants' understanding that rejection (i) is of primary importance for the purposes of this review since it relates to the priority date to which the claims are entitled and thus determines whether the reference cited in obvious rejection (ii) is prior art against the claims. Rejection (iii) is a provisional rejection and is expected to be withdrawn if all other issues are resolved.

(i) Priority

At pages 2-3 of the final Office Action, the Examiner maintained the assertion that priority application USSN 09/383,551 does not provide adequate support under 35 U.S.C. § 112 for claims 53-59, 64-66, 68, and 69. The present application is a continuation of USSN 10/301,056, filed November 21, 2002, which is a divisional of USSN 09/383,551, filed August 26, 1999.

A patent specification must describe an invention in sufficient detail so that one skilled in the art “can clearly conclude that the inventor invented the claimed invention.” Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571 (Fed. Cir. 1997). The purpose of the written description requirement is to “ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.” University of Rochester v. G. D. Searle & Co., Inc., 358 F.3d 916, 920 (Fed. Cir. 2004), quoting Reffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000). Compliance with the written description requirement is a fact-based inquiry that varies depending upon the nature of the invention claimed. Enzo Biochem, Inc. v. Gen-Probe Inc., on rehearing 323 F.3d 956, 963 (Fed. Cir. 2002). The subject matter of a claim need not be described in the specification *in haec verba* in order for the disclosure to satisfy the written description requirement. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000); see also In re Wilder, 736 F.2d 1516, 1520 (Fed. Cir. 1984) (stating that “[i]t is not necessary that the claimed subject matter be described identically, but the disclosure originally filed must convey to those skilled in the art that applicant had invented the subject matter later claimed”).

Independent claim 53 is directed to a method of identifying a substance that interacts with a polypeptide comprising an extracellular region (or a variant thereof in which one to ten amino acid residues are substituted, deleted or added) of the human JTT-1 protein of SEQ ID NO:2.

Applicants respectfully submit that the following passage from the specification (at page 115, line 21 to 26) contributes to the written description support of the claims (the underlined passage is particularly relevant to the claimed methods).

The genes (DNA), polypeptides, polypeptide fragments and antibodies of the present invention are useful not only as pharmaceuticals but also as reagents for searching molecules (ligands) interacting with the cell surface molecules of the present invention, clarifying the function of the ligand, and developing drugs targeting the ligands.

The purified polypeptide recited in claim 53 constitutes a “polypeptide of the invention” referenced in the foregoing passage (JTT-1 polypeptides and fragments and variants thereof are described in the specification at, e.g., page 15, lines 3-24, page 17, lines 5-16, and page 38, line 27, to page 43, line 8).

The passage from the specification identified above states that the polypeptides and polypeptide fragments of the invention are useful as reagents for searching for molecules that interact with the cell surface molecules of the invention. Claim 53 contains steps of contacting a purified JTT-1 polypeptide of the invention with a test substance and determining whether the test substance interacts with the polypeptide. The method steps of claim 53 are fundamental to screening protocols using purified polypeptides and are implicit in the specification's description of use of JTT-1 polypeptides in searching for molecules that interact with the cell surface molecules of the invention. A person of ordinary skill in the art reading the passages identified above would understand that searching for a molecule that “interacts” with a JTT-1 polypeptide inherently and necessarily entails contacting the polypeptide with a test substance and determining whether the test substance interacts with the polypeptide. On the other hand, methods that do not measure (directly or indirectly) an actual physical interaction between a molecule and the polypeptide would merely constitute a search for a candidate ligand. For example, *in silico* screening (which was mentioned in the Office Action) may be used to identify candidate binding molecules but is unable to determine conclusively whether a molecule “interacts” with a JTT-1 polypeptide. Any candidate binding molecule identified by an *in silico* screen could only be determined to be an actual “interacting” molecule by contacting the JTT-1

polypeptide with the molecule and determining whether the molecule interacts with the polypeptide.

Contrary to the assertions in the Office Action, the claimed methods are not mere obvious extensions of that which is disclosed in the application. Instead, a person of ordinary skill in the art reading the passages identified herein would readily understand the specification to implicitly describe the steps of contacting a JTT-1 polypeptide with a test substance and determining whether the test substance interacts with the polypeptide. The disclosure readily conveys to those skilled in the art that, as of the filing date of prior application USSN 09/383,551, the inventors had invented and were in possession of the currently claimed method (the specification of the present application is identical to that of prior application USSN 09/383,551). Consistent with the foregoing assertions, newly added claims may be supported in the specification through express, implicit, or inherent disclosure that allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed. MPEP § 2163. The specification need not describe the claimed subject matter identically in order to satisfy the written description requirement. Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323 (Fed. Cir. 2000).

In view of the foregoing comments, applicants respectfully submit that claims 53-59, 64-66, 68, and 69 are fully supported in the specification as filed and should be accorded the priority date of prior application USSN 09/383,551.

(ii) 35 U.S.C. §103(a) (Obviousness)

At pages 3-4 of the Office Action, claims 53-59, 64-66, 68, and 69 were finally rejected as allegedly obvious over Tamatani et al., U.S. Published Application No. 20020115831 ("Tamatani").

Tamatani belongs to the same patent family as the present application and claims priority to USSN 09/383,551. As detailed herein, independent claim 53 and the claims that depend therefrom are believed to be entitled to the priority date of prior application USSN 09/383,551. As a result, applicants respectfully submit that Tamatani does not constitute prior art against any of the pending claims and that the rejection should therefore be withdrawn.

(iii) Obviousness-Type Double Patenting

At page 4 of the Office Action, claims 53-59, 64-66, 68, and 69 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-24 of co-pending and commonly assigned application serial number 10/800,250.

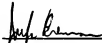
In view of the remarks presented herein, it is applicants' understanding that the provisional obviousness-type double patenting rejection is the only rejection remaining in the application. Accordingly, the double patenting rejection should be withdrawn to permit the present application to issue as a patent.

CONCLUSIONS

Applicants submit that all claims are in condition for allowance, which action is earnestly requested. Please apply any charges or credits to Deposit Account No. 06-1050, referencing Attorney Docket No. 14539-004012.

Respectfully submitted,

Date: May 23, 2007

  
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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number: 14539-004012
	Application Number 10/721,404	Filed November 25, 2003
	First Named Inventor Takuya Tamatani et al.	
	Art Unit 1644	Examiner Ilia I. Ouspenski

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this request.


This request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached sheets.

Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest.  
 See 37 CFR 3.71. Statement under 37 CFR 3.73(b)  
 is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record 47,443  
 (Reg. No.)
- ☐ attorney or agent acting under 37 CFR 1.34.  
 Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

  
 Signature

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 May 23, 2007  
 Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of no. forms are submitted.